



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,869	01/28/2004	William D. Huse	066797-0397	4128
41552	7590	12/29/2005	EXAMINER	
MCDERMOTT, WILL & EMERY			STEELE, AMBER D	
4370 LA JOLLA VILLAGE DRIVE, SUITE 700			ART UNIT	
SAN DIEGO, CA 92122			PAPER NUMBER	

1639

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/767,869

Applicant(s)

HUSE, WILLIAM D.

Examiner

Amber D. Steele

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Status of the Claims***

1. Claims 1-75 are currently pending.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8 are drawn to a composition of cells, classified in class 435, subclass 41.
  - II. Claims 9-15 are drawn to a composition of vectors, classified in class 435, subclass DIG 22.
  - III. Claims 16-25 are drawn to a cloning composition, classified in class 435, subclass 69.1.
  - IV. Claims 26-33 are drawn to an expression vector library, classified in class 435, subclass DIG 24.
  - V. Claims 34-43 are drawn to a method of constructing a library of vectors, classified in class 435, subclass DIG 46.
  - VI. Claims 44-54 and 64-65 are drawn to a method for selecting a heteromeric receptor, classified in class 435, subclass DIG 2.
  - VII. Claims 55-63 are drawn to a method for determining nucleic acid sequences, classified in class 435, subclass 6.
  - VIII. Claims 66-70 are drawn to a vector of SEQ ID No. 1, classified in class 435, subclass 320.1.

IX. Claims 71-75 are drawn to a vector of SEQ ID No. 5, classified in class 435, subclass 320.1.

3. The inventions are independent and/or distinct, each from the other because of the following reasons:

A. Inventions I-IV and VIII-IX are drawn to independent and/or patentably distinct products since these products have different chemical structures and/or functions. Therefore, Groups I-IV and VIII-IX have different issues regarding patentability and enablement. Additionally, Groups I-IV and VIII-IX represent patentably distinct subject matter which merits separate and burdensome searches. Art anticipating or rendering obvious Group I would not necessarily anticipate or render obvious Group II-IV and VIII-IX or *vice versa*, because they are drawn to different inventions that have different distinguishing features. Furthermore, Groups I-IV and VIII-IX have a separate status in the art as shown by the different classification (e.g. subclass; please refer to section 2).

B. Groups V-VII represent separate and patentably distinct inventions. Groups V-VII are drawn to different methods that are directed to different purposes, recite different method steps, and/or use different materials. Therefore, Groups V-VII have different issues regarding patentability and enablement. Additionally, Groups V-VII represent patentably distinct subject matter which merits separate and burdensome searches. Art anticipating or rendering obvious Group V would not necessarily anticipate or render obvious Group VI-VII and *vice versa*, because they are drawn to different inventions that have different distinguishing features. Furthermore, Groups V-VII have a

Art Unit: 1639

separate status in the art as shown by the different classification (e.g. subclass; please refer to section 2).

C. Inventions II, IV-V, and VIII-IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process (e.g. method of using a retroviral vector to construct a library of vectors). In addition, Groups II, IV, and VIII-IX have been shown to be separate and patentably distinct inventions (please refer to section 3 A above).

D. Inventions I, III, and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the products as claimed can be practiced with another materially different product (e.g. retroviral vectors). In addition, Groups I and III have been shown to be separate and patentably distinct inventions (please refer to section 3 A above).

E. Inventions I-IV, VI, and VIII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

Art Unit: 1639

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the products as claimed can be practiced with another materially different product (e.g. retroviral vectors). In addition, Groups I-IV and VIII-IX have been shown to be separate and patentably distinct inventions (please refer to section 3 A above).

F. Inventions I-IV and VII-VIII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the products as claimed can be practiced with another materially different product (e.g. retroviral vectors). In addition, Groups I-IV and VIII-IX have been shown to be separate and patentably distinct inventions (please refer to section 3 A above).

4. Because these inventions are distinct for the reasons given above and:
  - a. have acquired a separate status in the art as shown by their different classification (please refer to paragraph 1), and/or
  - b. divergent subject matter which would require different bibliographic and/or classification searches; and/or

c. because the inventions have acquired a separate status in the art because of the recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***Species Election***

5. This application contains claims directed to the following patentably distinct species of the claimed inventions for Groups I-VII. Election is required as follows.

6. If applicant elects the invention of **Group I**, the applicant is required to elect a single, specific species from **each** of the following species A-B.

A. species of heteromeric receptor (see claims 3 and 5)

Applicant must elect, for the purposes of search, a **single, specific species** of heteromeric receptor.

B. species of bacteriophage

Applicant must elect, for the purposes of search, a **single, specific species** of bacteriophage.

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

7. If applicant elects the invention of **Group II**, the applicant is required to elect a single, specific species from **each** of the following species.

A species of bacteriophage

Applicant must elect, for the purposes of search, a **single, specific species** of bacteriophage.

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

8. If applicant elects the invention of **Group III**, the applicant is required to elect a single, specific species from **each** of the following species A-B.

A. species of heteromeric receptor (see claims 18 and 20)

Applicant must elect, for the purposes of search, a **single, specific species** of heteromeric receptor.

B. species of bacteriophage

Applicant must elect, for the purposes of search, a **single, specific species** of bacteriophage.



It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

9. If applicant elects the invention of **Group IV**, the applicant is required to elect a single, specific species from **each** of the following species A-B.

A. species of heteromeric receptor (see claims 28 and 30)

Applicant must elect, for the purposes of search, a **single, specific species** of heteromeric receptor.

B. species of bacteriophage

Applicant must elect, for the purposes of search, a **single, specific species** of bacteriophage.

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

Art Unit: 1639

10. If applicant elects the invention of **Group V**, the applicant is required to elect a single, specific species from **each** of the following species A-B.

A. species of heteromeric receptor (see claims 36-37)

Applicant must elect, for the purposes of search, a **single, specific species** of heteromeric receptor.

B. species of bacteriophage

Applicant must elect, for the purposes of search, a **single, specific species** of bacteriophage.

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

11. If applicant elects the invention of **Group VI**, the applicant is required to elect a single, specific species from **each** of the following species A-B.

A. species of heteromeric receptor (see claims 46 and 47)

Applicant must elect, for the purposes of search, a **single, specific species** of heteromeric receptor.

B. species of bacteriophage

Art Unit: 1639

Applicant must elect, for the purposes of search, a **single, specific species** of bacteriophage.

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

12. If applicant elects the invention of **Group VII**, the applicant is required to elect a single, specific species from **each** of the following species A-B.

A. species of heteromeric receptor (see claims 57 and 59)

Applicant must elect, for the purposes of search, a **single, specific species** of heteromeric receptor.

B. species of bacteriophage

Applicant must elect, for the purposes of search, a **single, specific species** of bacteriophage.

It would necessarily be unduly burdensome to search each of the above species of the presently claimed methods since it would entail different and separately burdensome manual/computer bibliographic searches in the patent and nonpatent literature databases and/or

Art Unit: 1639

additionally a reference against one species may not necessarily anticipate or render obvious the other and/or the different species may elicit different issues under 35 U.S.C. 112.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, **including any claims subsequently** added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

15. Should applicant traverse on the grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR

1.143). Because the above restriction/election requirement is complex, a telephone call to applicant to request an oral election was not made. See MPEP § 812.01.

17. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may

Art Unit: 1639

result in a loss of the right to a rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Future Correspondences***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS

December 12, 2005

  
**ANDREW WANG**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**